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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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KERYX BIOPHARMACEUTICALS, INC.,

Plaintiff,

- against - 07 Civ. 10376 (CSH)

PANION & BF BIOTECH, INC.,

Defendant.

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**MEMORANDUM OF LAW IN SUPPORT OF THE PLAINTIFF'S MOTION BY ORDER TO SHOW CAUSE FOR A PRELIMINARY INJUNCTION AND APPLICATION FOR EXPEDITED DISCOVERY AND PRETRIAL PROCEEDINGS, AND EXPEDITED ADJUDICATION OF ITS CLIAMS**

Plaintiff Keryx Pharmaceuticals, Inc. ("Keryx") submits this memorandum of law, together with the accompanying declarations of Michael S. Weiss (the "Weiss Decl.") and Gregg L. Weiner (the "Weiner Decl.") in support of its motion, pursuant to Fed. R. Civ. P. 16, 30(a), 33(a), 34(b) and 65(a), for preliminary injunctive relief in Keryx's favor and application for expedited discovery and adjudication of the action. As detailed in the Weiss Declaration, Keryx will face irreparable injury if a preliminary injunction hearing is not scheduled quickly, and will also face irreparable injury if the merits of its case are not decided upon before January 30, 2008.

## BACKGROUND

The relevant facts are set forth in the declaration of Keryx's CEO and Chairman, Michael Weiss, dated to November 19, 2007, and the exhibits attached thereto, and in the declaration of Gregg L. Weiner dated November 19, 2007, with attached exhibits.

Keryx is a publicly traded pharmaceutical company whose business includes the development and commercialization of medically important pharmaceutical products for the treatment of serious conditions, including diabetes, cancer, and renal (kidney) disease. (Weiss Decl. ¶ 2.) Under an exclusive patent license (the "License Agreement") from Panion & BF Biotech, Inc. ("Panion"), dated November 7, 2005, Keryx is developing a chemical compound, ferric citrate, as a pharmaceutical for treatment of disease. (Id ¶ 3; Exh. 1.) Under the License Agreement, Keryx's exclusive rights to develop and commercialize ferric citrate extend throughout most of the world, including the United States, Japan, and Canada, and include the right to grant sublicenses to third parties. (Weiss Decl. ¶ 3; Exh. 1.)

The License Agreement is an important corporate asset of Keryx, and Keryx has devoted substantial corporate resources and incurred substantial expenses in performing two categories of development work for ferric citrate. (Id. ¶ 4.) The first category includes work undertaken to

generate information that is needed for successful commercialization of ferric citrate as a pharmaceutical. These information-generating development activities do not result in Keryx being supplied with ferric citrate. BRI Pharmaceutical Research, Inc. ("BRI"), BioVectra DCL ("BioVectra"), and the PharmPro Services division of Fluid Air, Inc. ("PharmPro"), as contractors are assisting Keryx with this development work. (Id. ¶ 4.) Section 3.1 of the License Agreement expressly authorizes Keryx to use Panion-owned technology ("Licensor Know-How") to "develop, have developed, make [and] have made" the licensed product. (Id. Exh. 1.) Panion has not accused Keryx of breaching the License Agreement by performing this first category of information-generating work. (Id. ¶ 5.)

The second category of development work for ferric citrate concerns work that involves providing a supply of ferric citrate ("Clinical Supplies") to Keryx, for use in toxicology testing and clinical trials. The License Agreement provides in Section 7.7 that during an exclusive supply period (which has not yet expired), and subject to certain conditions, Keryx and its sublicensees shall obtain their supply of the Clinical Supplies exclusively from Panion, subject to certain price competition provisions. (Id. ¶ 6; Exh. 1.)

On September 18, 2007, Keryx advised Panion that it was about to grant an exclusive sublicense for Japan (the "Japanese Sublicense") to Japan Tobacco, Inc. and Torii Pharmaceutical Co. Ltd. (collectively, "Japan Tobacco") and asked Panion to sign a consent form for the comfort and assurance of the sublicensees (even though Panion's consent was not contractually required). (Id. ¶ 7.) Panion declined to sign the consent form, and the Japanese Sublicense was nevertheless executed, with effect from September 26, 2007, for an upfront licensing fee of $12 million plus future milestone payments and royalties, collectively estimated to be worth $100 million. (Id. ¶ 7.)

On September 22, 2007, after learning about the Japanese Sublicense, Panion for the first time accused Keryx of having breached the License Agreement by ordering certain supplies of ferric citrate in 2006 from BioVectra.[1] (Id. ¶ 8.) On October 31, 2007, Panion's counsel, Albert Wai-Kit Chan, emailed to Keryx a notice contending that Keryx's orders in 2006 constituted "a material breach" of the License Agreement that "has not been cured for more than ninety days" and threatening to "take appropriate actions to nullify th[e] agreement." (Id. ¶ 8; Exh. 2.) Section 12.3 of the License Agreement permits termination for cause only if Keryx fails to cure a material breach within ninety days after Panion has given written notice of default. (Id. Exh. 1.) Panion has not retracted its false claim that the ninety-day cure period has expired or its threat to terminate the License Agreement. (Id. ¶ 8.)

On or about November 7, 8 and 9, 2007, Panion's counsel contacted Keryx's contractors, BRI, BioVectra and PharmPro, demanding that they cease the work they are performing for Keryx, on the grounds that they are using Panion-owned technology, and threatening to commence proceedings against them unless they agreed to do so. (Id. ¶ 9; Id. Exhs. 3, 4, 5) That work includes the information-gathering development work that Keryx is authorized under the License Agreement to do or have done. (Id. ¶ 9.)

On November 12, 2007, counsel for Keryx wrote to Panion's counsel, explaining that Keryx believed it had not breached the License Agreement, giving an assurance that during the Exclusive Supply Period, Keryx would submit future orders for Clinical Supplies of ferric citrate to Panion in accordance with Section 7.7(b) of the License Agreement, and asking Panion to confirm that this sufficed to cure the alleged breach or else to state what else was needed to cure.

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[1] Keryx denies that it has breached the License Agreement and at the appropriate time will show that to be so, and that Panion knew about and did not object to the acts that Panion now denominates as a breach.

Keryx also asked Panion to cease and desist from threatening Keryx's contractors. (Id. ¶ 10; Weiss Decl. Exh. 2.)

Panion did not reply to the November 12, 2007 letter, but instead repeated and escalated its threats and demands to BRI, BioVectra and PharmPro, and on November 15, 2007 filed a Summons with Notice in New York Supreme Court, Queens County, purporting to assert claims against BRI and seeking to enjoin BRI from continuing its contract work for Keryx. (Weiner Decl. Exh. 6.)

Panion also is refusing to consult in good faith with Keryx and its sublicensee concerning the prosecution in Japan of the patent rights that Panion licensed to Keryx and that Keryx has in turn sublicensed to Japan Tobacco. (Weiss Decl. ¶ 12.) Section 8.1.1 of the License Agreement provides that Panion shall "use reasonable efforts to prosecute the patent applications" that are included in the license and shall "regularly consult with Licensee and shall keep Licensee advised of the status of all patents and patent applications relating to the Patent Rights . . . " (Id. ¶ 12; Id. Exh. 1.) Japan Tobacco's patent counsel was initially permitted to meet with Panion's Japanese patent counsel to discuss how to respond to a Notice of Office Action issued by the Japanese Patent Office, to which a response will be due on November 28, 2007 unless that deadline is extended. (Id. ¶ 12.) Panion has now instructed its Japanese patent counsel not to communicate with Japan Tobacco's counsel. (Id. ¶ 12; Exh. 2.) In addition, having agreed on October 24, 2007 to request a three-month extension of the deadline for responding to the Notice of Office Action, which Japanese counsel believes is important to procuring a patent in Japan, Panion switched course and informed Keryx that it would not seek the extension "based on the unresolved issues between Keryx and Panion." (Weiss Decl. ¶ 12; Weiss Decl. Exh. 6.) Panion's actions threaten to cause Keryx irreparable harm.

## ARGUMENT

### I. THE COURT SHOULD SCHEDULE A HEARING FOR NO LATER THAN NOVEMBER 27, 2007 ON PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTIVE RELIEF

Keryx seeks a prompt hearing and ruling on its preliminary injunction application with respect to the following actions by Panion that threaten irreparable harm to Keryx: (1) Panion's failure to consult in good faith with Keryx concerning prosecution of licensed patent applications, including failure to seek the agreed three-month extension for responding to the Japanese patent office and to allow contact between Panion's Japanese patent counsel and the patent counsel of Keryx's sublicesee Japan Tobacco; (2) Panion's interference with Keryx's activities related to the development of the Product under the License Agreement; and (3) Panion's threat to serve notice of termination, prior to January 30, 2008, with respect to the License Agreement. Each of these actions violates Keryx's rights under the License Agreement and threatens Keryx with irreparable harm.

Keryx must be allowed to exercise its rights under the License Agreement without the threat of wrongful early notice of termination. Keryx has not breached the License Agreement. But even if it had, as alleged by Panion, Keryx expressly has until January 29, 2008 to cure the breach (with any termination of the License not effective for an additional 90 days thereafter). (Weiss Decl. ¶ 8; Exh. 1, 2.) Unfortunately, Panion is acting as if the License Agreement has already been terminated, thus forcing Keryx to seek emergency relief to stop Panion's improper actions.

Keryx urgently needs Panion to comply with its duty under the License Agreement to cooperate with Keryx and its sublicensee in prosecuting the Japanese patent application, and to seek the three-month extension of the November 28, 2007 deadline for responding to the Japan

patent office to which Panion previously agreed, because successful prosecution of the Japanese patent application is critical to commercial development under the Japanese Sublicense. Any failure to obtain the Japanese patent will harm Keryx immensely and in ways not capable of being remedied by a judgment for money damages. See Weiss Decl. ¶12.

Second, it is imperative that BRI, BioVectra and PharmPro be allowed to continue their work with Keryx to develop the Licensed Product without Panion's interference, which will inevitably cause delays and disruptions and irreparably harm Keryx. Panion's threats against Keryx's contractors performing activities which Keryx is licensed to perform, and as to which Panion has not objected before, must be enjoined promptly. Any delay in the approval or launch of the final drug will result in a shortened period of time during which Keryx can sell its product before it becomes exposed to generic competition. In addition, delay in launching the drug will cause Keryx to lose ground in the race against competing companies to bring the drug to market; and once lost, that lead time can never be recovered.

Finally, a premature notice terminating the License Agreement -- and purporting to cut off Keryx's opportunity to cure any alleged breach -- would cast a cloud over the Japanese Sublicense, causing severe and irreparable injury to Keryx, including by delaying the development work needed to obtain regulatory approval for ferric citrate in Japan and by causing reputational injury to Keryx in Japan. (Weiss Decl. ¶ 14.)

Courts regularly have found each of the types of harms threatened here to constitute irreparable harm. See, e.g., Reuters Ltd. v. United Press Intern., Inc., 903 F.2d 904 (2d Cir. 1990) (termination of delivery of a unique product to a distributor whose customers expected and relied on distributor for continuous supply of the product found to cause irreparable damage to the good will of the distributor); U.S. Ice Cream Corp. v. Carvel Corp., 136 A.D.2d 626, 523

N.Y.S.2d 869 (2d Dep't 1988) (harm threatened by termination of exclusive license and interference with the licensee's suppliers found to be irreparable); Dynamic Solutions, Inc. v. Planning & Control, Inc., 646 F. Supp. 1329 (S.D.N.Y. 1986) (damages threatened by wrongful deprivation of party's economic leverage resulting from its copyrights were difficult to quantify and thereby found to be irreparable); Freedom Holdings, Inc. v. Spitzer, 447 F. Supp. 2d 230, 262-63 (S.D.N.Y. 2004) (loss of market share difficult to quantify and representing loss of opportunity found to be irreparable injury).

Under the circumstances, the Court should schedule a prompt preliminary injunction hearing. See, e.g., Time Warner Cable v. Bloomberg L.P., 1997 U.S. App. LEXIS 26237 (2d Cir. 1997) (preliminary injunction hearing scheduled twelve days after plaintiff's motion for same); Merrill Lynch v. Coffindaffer, 183 F. Supp. 2d 842 (D. W. Va. 2000) (preliminary injunction hearing scheduled twelve days after plaintiff's motion for same); Energetics Sys. Corp. v. Advanced Cerametrics, 1996 U.S. Dist. LEXIS 2830 (D. Pa. 1996) (preliminary injunction hearing scheduled for twenty-one days after motions for expedited discovery).

Given the nature of Keryx's claims and the imminent irreparable harm that the defendant threatens to cause, a prompt hearing on plaintiff's prayer for preliminary injunctive relief is both warranted and appropriate, and should be scheduled for no later than November 27, 2007.

## II. THE COURT SHOULD ORDER EXPEDITED DISCOVERY AND PROMPT ADJUDICATION OF KERYX'S CLAIMS

The Federal Rules of Civil Procedure provide that the Court has a duty to ensure the just, speedy, and inexpensive determination of every action. See Fed. R. Civ. P. 1. To that end, the Rules give the Court broad discretion to expedite the disposition of an action, including the discretion to expedite the discovery process through a scheduling order. See Fed. R. Civ. P. 16;

see also Torres v. Puerto Rico, 485 F.3d 5, 9 (1st Cir. 2007) ("We begin with bedrock: trial judges have an abiding responsibility for the efficient management of the cases on their dockets. To that end, the Civil Rules require a district judge to issue orders 'as soon as practicable' fixing deadlines for the completion of discovery and the filing of dispositive motions," citing Fed. R. Civ. P. 16(b)).

In this action, an expedited trial schedule and proceedings are absolutely necessary to ensure that there is a determination of Keryx's claims before the cure period expires on January 30, 2008 and for the reasons set forth above explaining the unwarranted risk of irreparable harm faced by Keryx.

Expedited discovery requests are assessed "under the flexible standard of reasonableness and good cause." Ayyash v. Bank Al-Madina, 233 F.R.D. 325, 327 (S.D.N.Y. 2005) (Lynch, J.) Furthermore, this Court has consistently recognized that expedited discovery is necessary and appropriate where, as here, substantial commercial interests are at stake. See, e.g., E.ON AG v. Acciona, S.A., 2007 U.S. Dist. LEXIS 7771 (S.D.N.Y. 2007). Keryx's request for expedited discovery is both reasonable and supported by good cause.

Panion has no basis to object to expedited resolution of this matter. Accelerated determination is in the interest of all concerned, to clarify rights and duties of the parties under the highly valuable License Agreement. Panion should not object to expedited discovery and proceedings because it has already expressed a desire for expedited determination of these issues -- in the form of immediate threats to terminate the License Agreement and stop activity by Keryx's contractors, and by filing its own action in New York State court last week purporting to seek emergency relief on one of the precise issues raised in this matter (but not against Keryx). Furthermore, expedited discovery and proceedings will not present a hardship to Panion because

it and its counsel are fully familiar with the events that are the subject of this action, having already served a notice of default and filing its own court action.

The Court should, therefore, grant expedited discovery and schedule a prompt trial as requested so that the Court may render the most informed and expedient decision possible on the merits of Keryx's claims. The standard time periods specified in the Federal Rules of Civil Procedure are unrealistically protracted in this context, and Rules 30(a), 33(a), 34(b) of the Federal Rules of Civil Procedure clearly authorize the expedited discovery sought.

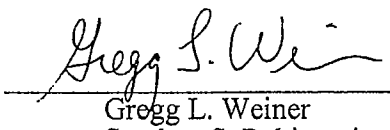
## CONCLUSION

For the reasons set forth above, Keryx's motion should be granted in all respects.

Dated: New York, New York
November 19, 2007

Respectfully submitted,

FRIED, FRANK, HARRIS, SHRIVER
& JACOBSON LLP

By: 

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